



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,881	05/27/2005	Fumihiko Kanai	00005.001261	8308

5514 7590 09/13/2007
FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
----------	--------------

1626

MAIL DATE	DELIVERY MODE
-----------	---------------

09/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,881

Applicant(s)

KANAI ET AL.

Examiner

Rei-tsang Shiao, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/20/05.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This application claims benefit of the foreign application: JAPAN 2002-351345 with a filing date 12/03/2002. However, an English-translated version of the instant certified copy of the foreign priority document has not been filed to the Office. The instant foreign priority has not been granted.
2. Claims 1-22 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on September 20, 2005 has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Responses to Election/Restriction

4. During a telephone conversation with Lawrence S. Perry on September 10, 2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-22, in part. An election of compound No. 21 as a single species is also acknowledged. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-22 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1-22, in part, drawn to compounds/compositions of formula (I) or (II), wherein the variable R¹ represents aryl or a heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R² contains a heteroaryl or

Art Unit: 1626

heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof, and their methods of use.

Claims 1-22, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-22, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5.1 Claims 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17-22 provide for the use of compounds of formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17-22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

Art Unit: 1626

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

5.2 Claims 1, 3-5, 11-13 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is recited as a compound claim and use the term "comprising" which is open-ended, see line 1. A compound claim cannot use open-ended language when defining the parameters of the compound, see M.P.E.P. 2111.03. Dependent claims 3-5, 11-13 and 17-19 are also rejected along with claim 1 under 35 U.S.C. 112, second paragraph. By deleting "A JNK (c-jun N-terminal kinase) inhibitor comprising, as an active ingredient", the rejection would be overcome.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using compounds of the formula (I) or (II) for treating cells *in vitro*, it does not reasonably provide enablement of methods of use using compounds or therapeutic agents of formula (I) or (II) for treating or preventing a disease *in vivo* (e.g., treating Parkinson's diseases or Alzheimer's disease). The specification does not enable any person skilled in the art to which it pertains, or with

Art Unit: 1626

which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention of claims 3-22 is intent methods of use (i.e., treatment or prevention) using compounds of the formula (I) or (II) or therapeutic agents (e.g. treating a subject) *in vitro* or *in vivo*. The instant methods of use are using compounds of formula (I) or (II), wherein the variable R¹ represents aryl or a heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R² contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group

Art Unit: 1626

consisting of pyridine, indole, thiophene or pyrimidine thereof.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. Kania et al. US 6,534,524 disclose similar indazole compounds of Formula (I) as agents treating angiogenesis, see columns 387-392.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming intent methods of use (i.e., treatment or prevention) using compounds or therapeutic agents of the formula (I) or (II) effective against cells *in vitro* or *in vivo*. As such, the specification fails to enable the skilled artisan to use the compounds of the formula (I) or (II) for treating or preventing diseases. In addition, there is no proof that the claimed compounds of the formula (I) or (II) to treat or prevent disease, in a human or to an animal model.

In addition, there is no established correlation between *in vitro* activity and

Art Unit: 1626

accomplishing treating diseases other than pain or inflammation, *in vivo*, and those skilled in the art would not accept allegations in the instant specification to be reliable predictors of success, and those skilled in the art would not be able to use the instant compounds since there is no description of an actual method wherein diseases in a host are treated or prevented.

Hence, one of skill in the art is unable to fully predict possible results from the administration of the instant compounds of the claims due to the unpredictability of the treatment or prevention of diseases. Diseases being treated or prevented without disclosing experimental data are known to have many obstacles that would prevent one of ordinary skill in the art from accepting treating or preventing regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the listing of exemplary cell-based assay of enzyme inhibitory activity in terms of IC_{50} , or a cell apoptosis suppressive activity in terms of percentage inhibition, *in vitro*, see pages 34-36 of the specification. There are no *in vivo* working examples present for the treatment of diseases by the administration of the instant compounds of the instant invention. In the instant case, there are no *in vivo* working examples present for the treatment or prevention of diseases by administration the instant compounds of formula (I) or (II).

The breadth of the claims

The breadth of the claims is intent methods of use using the compounds or therapeutic agents of the formula (I) or (II) effective treating or preventing diseases. Moreover, there is no reasonable basis for assuming the instant compounds of formula (I) or (II), wherein the variable R^1 represents aryl or a heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R^2 contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof embraced by the claims will share the same physiological properties. Moreover, the instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include any methods of use related to brain neurodegenerative disorders using compounds of formula (I) or (II), which may be discovered in the future.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what disease would be benefited (i.e., treated or prevented) by the administration of the instant compounds or therapeutic agents of the formula (I) or (II), wherein the variable R^1 represents aryl or a heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R^2 contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof of the instant invention and would furthermore then have to determine which of the claimed methods of use

Art Unit: 1626

using the instant compounds would provide treatment or prevention of any diseases, if any.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of the instant claims for the treatment or prevention of diseases other than pain or inflammation or blocking sodium channels without limitation. As a result necessitating one of skill to perform an exhaustive search for which diseases, can be treated by what compounds or therapeutic agents of the formula (I) or (II), wherein the variable R¹ represents aryl or a heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R² contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof. As a result necessitating one of skill to perform an exhaustive search for which diseases can be treated or prevented by what compounds or therapeutic agents of the instant claims in order to practice the claimed invention.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the

Art Unit: 1626

instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds in regards to the treatment or prevention of nerve diseases, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success. This rejection can be overcome by incorporation of the treating condition (i.e., *in vitro*) and deleting "prevention" from claims 30-22 respectively would obviate the rejection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

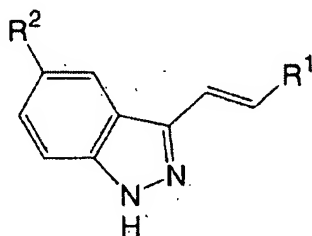
Art Unit: 1626

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Applicants claims compounds/compositions of formula (I) or (II),



i.e.,

, wherein the variable R¹ represents aryl or a

heterocyclic group and the heterocyclic group is selected from pyridine thereof; when

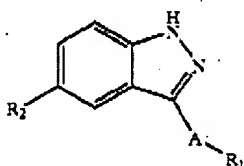
Art Unit: 1626

the variable R^2 contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof, and their methods of use (i.e., JNK inhibitor).

7.1 Claims 1-22 are rejected under 35 U.S.C. 103(a) as being obvious over Bhagwat et al. WO 02/10137.

Determination of the scope and content of the prior art (MPEP §2141.01)

Bhagwat et al. disclose compound/composition of formula (I) as JNK inhibitors,



i.e., R2c1ccc2c(c1)c(c[nH]2)A-R1, wherein the variable A represents $-(CH_2)_bCH=CH-$ $(CH_2)_c-$ and the variable b or c independently represents 0, the variable R_1 represents aryl, heterocycle fused to phenyl, or heteroaryl (i.e., pyridyl), the variable R_2 represents $-R_3$ (i.e. carboxy), $-R_4$ (i.e., NR_8R_9 and R_8 or R_9 represents hydrogen or alkyl or heteroaryl), $-(CH_2)_bC(=O)NR_5R_6$, or $-(CH_2)_bOR_5$, and the variable b is 0, R_5 or R_6 independently represents hydrogen, optionally substituted alkyl, aryl, heterocycle and the substituents are 1-4 R_3 , and R_3 represents hydroxyl, carboxy, alkyl or alkoxy, see pages 7-9.

Determination of the difference between the prior art and the claims (MPEP

§2141.02)

Art Unit: 1626

The difference between the instant claims and Bhagwat et al. is that the instant variable R¹ represents aryl or heterocyclic group (i.e., pyridyl), while Bhagwat et al. represents aryl, heterocycle fused to phenyl, or heteroaryl (i.e., pyridyl) at the same position. Bhagwat et al. compounds/compositions overlap with the instant invention.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-22 prima facie obvious **because** one would be motivated to employ the compounds/compositions of Bhagwat et al. to obtain the instant compounds/composition of formula (I) or (II), wherein the variable R¹ represents aryl or a heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R² contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof, and their methods of use

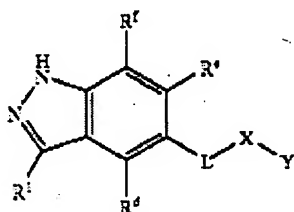
The motivation to obtain the claimed compounds/compositions derives from known Bhagwat et al. compounds/compositions would possess similar activities (i.e., JNK inhibitors) to that which is claimed in the reference.

7.2 Claims 1-22 are rejected under 35 U.S.C. 103(a) as being obvious over Ohi et al. US 2005/0261339 A1.

Determination of the scope and content of the prior art (MPEP §2141.01)

Ohi et al. disclose compounds/compositions of formula (III), i.e.,

Art Unit: 1626



, wherein the variable R_d , R_e and R_f independent represents hydrogen, the variable R_1 represents $-(CO)_h-(NR_a)_j-(CR_b=CR_c)_k-Ar$ and the variable h or j is 0 and the variable k is 1, the variable Ar represents aryl or heteroaryl (i.e., pyridyl), the variable L represents a single bond; or optionally substituted C_{1-6} alkylene, C_{2-6} alkenylene or C_{2-6} alkynylene group, the variable X represents a single bond, $-NR^7$, $-CO-NR^8-Z$, $C(O)O-$ or $-CO-$, the variable y represents a single bond, hydrogen, hydroxyl, carboxyl, see columns 7-8 or 313-314.

Determination of the difference between the prior art and the claims (MPEP

§2141.02)

The difference between the instant claims and Ohi et al. is that the instant variable R_2 represents hydrogen, carboxy or NR^3R^4 , while Ohi et al. represents a single bond, hydrogen or carboxy at the same position. Ohi et al. compounds/compositions overlap with the instant invention.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-22 prima facie obvious **because** one would be motivated to employ the compounds/compositions of Ohi et al. to obtain the instant compounds/composition of formula (I) or (II), wherein the

Art Unit: 1626

variable R¹ represents aryl or a heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R² contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof, and their methods of use

The motivation to obtain the claimed compounds/compositions derives from known Ohi et al. compounds/compositions would possess similar activities (i.e., JNK inhibitors) to that which is claimed in the reference.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

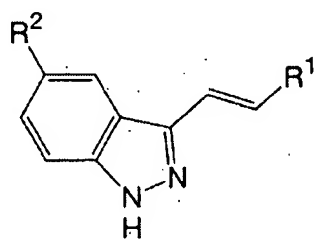
Effective January 1, 1994, a registered attorney or agent of record may sign a

Art Unit: 1626

terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 6 of Kanai et al. co-pending allocation No. 10/548,475, or over claims 1,24, 67, and 72 of Kanai et al. co-pending allocation No. 10/548,592. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claims compounds/compositions of formula (I) or (II),

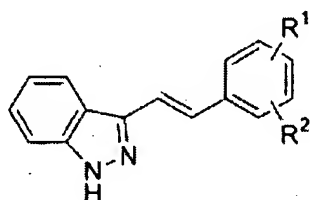


i.e.,

, wherein the variable R¹ represents aryl or a

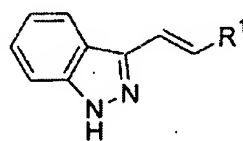
heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R² contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof, and their methods of use (i.e., JNK inhibitor).

Kanai et al. '475 or '592 independently claim compounds/compositions of formula



(I), i.e.,

or

, wherein the variable R¹ of

Art Unit: 1626

'592 represents aryl or heterocyclic group (i.e., pyridyl).

The difference between the instant claims and Kanai et al. is that the instant variable R² represents hydrogen, carboxy or NR³R⁴, while Kanai et al. represents hydrogen at the same position. Kanai et al. compounds/ compositions overlap with the instant invention.

One having ordinary skill in the art would find the instant claims 1-22 *prima facie* obvious **because** one would be motivated to employ the compounds/compositions of Kanai et al. to obtain the instant compounds/composition of formula (I) or (II), wherein the variable R¹ represents aryl or a heterocyclic group and the heterocyclic group is selected from pyridine thereof; when the variable R² contains a heteroaryl or heteroaroyl and the heteroaryl or heteroaroyl is selected from the group consisting of pyridine, indole, thiophene or pyrimidine thereof, and their methods of use

The motivation to obtain the claimed compounds/compositions derives from known Kanai et al. compounds/compositions would possess similar activities (i.e., JNK inhibitors) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection.

Claim Objections

10. Claims 1-22 are objected to as containing non-elected subject matter, i.e., heterocyclic group, heteroaroyl, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

Art Unit: 1626

11. Claims 1-22 are objected to because of the following informalities: Claims 1-2 recite the symbols "[", "]", "(", or ")" independently, i.e., see line 5, 8, 11 or 16 of claim 1. Replacement of the symbol "[", "]", "(", or ")" with a symbol "," would obviate the objection.

12. Claims 3-8 and 10 are objected to for being substantial duplicates of the claims from which they depend. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1626

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rei-tsang Shiao, Ph.D.
Patent Examiner
Art Unit 1626

September 11, 2007